



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/848,249

05/03/2001

David F. Woodward

D2910

6273

33197

7590

10/21/2004

STOUT, UXA, BUYAN & MULLINS LLP  
4 VENTURE, SUITE 300  
IRVINE, CA 92618

EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/848,249

**Applicant(s)**

WOODWARD ET AL.

**Examiner**

Zohreh Fay

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 and 25 is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-17 and 20-23 is/are rejected.
- 7) ☒ Claim(s) 18 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

Art Unit: 1614

Claims 1, 2, 3-13 and 15-25 are presented for examination

The amendments and remarks filed on May 12, 2004 have been received and entered.

Claims 1, 2, 5, 6, 9-13, 15-17, 20-21 are rejected under 35 U.S.C. 102 (b) as being anticipated by DeSantis Jr. et al. for the reasons set forth on page 2, of the office action of February 12, 2004.

Claims 1, 2, 4-8, 15-17, 20- 22 and 23 are rejected under 35 U.S.C. 103 as being unpatentable over Neumann (U.S. Patent 4,188,393) and WO 0044/355.

Neumann teaches the use of the claimed alpha2 adrenergic agonist in a pharmaceutical formulation. The above reference also teaches that such compounds can be used in an acid addition salt form. See column 3, lines 44-60. The WO Patent teaches the use of alpha2 adrenergic agonist in combination with a fatty acid in a pharmaceutical formulation. See page 4, lines 22-28, page 7 lines 18-22, page 10 lines 11-13, page 20 example IL, page 22 example 2 and page 23 lines 2-6. The above reference differs from the claimed invention in the specific fatty acids of claims 7 and 8 and the specific agonist and acid of claims 22 and 23. It would have been obvious to a person skilled in the art to substitute one fatty acid for another, considering that the prior art on page 22, example 2, teaches the use of different fatty acids within the chain length of the claimed invention in combination with alpha-2 adrenergic agonist.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of the claimed alpha2 adrenergic agonist which can be used in combination with acids in a salt form and the other relates to the addition of the claimed fatty acids to the alpha2 adrenergic agonist as old. The

Art Unit: 1614

formation ion-pair complex between the chemical components being used in combination is considered to be within the skill of the art in the absence of evidence to the contrary.

Applicant's arguments and remarks have been Carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the iron-pair complex between the alpha2 adrenergic agonist and the fatty acids. The allegation is not well taken. Since the prior art teaches that such components have been used together, therefore to form an ion-pair complex between chemical components being used together is considered to be within the skill of artisan.

Claims 24 and 25 at present time are considered to be allowable.

Claims 18 and 19 are objected to as being dependent on a rejected claim.

The amendments of May 12, 2004 necessitates the new ground for rejection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

A handwritten signature in black ink, appearing to read "Zohreh Fay", is located in the bottom right corner of the page.